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BEFORE THE UNITED STATE HOUSE OF REPRESENTATIVES
COMMITTEE ON GOVERNMENT REFORM

REGARDING THE IMPLEMENTATION OF PROJECT BIOSHIELD AND THE STATE OF BIODEFENSE IN THE UNITED STATES

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Chairman Davis, Congressman Waxman and Members of the Committee, it is an honor for me to testify before you today regarding the current state of the implementation of the Project BioShield Act of 2004. I am Bob Kramer, President and Chief Executive Officer of BioPort Corporation. Let me begin by thanking the Committee for its leadership in this critical public health and national security area. The bipartisan work of this Committee's members, including the leadership of Chairman Davis and Congressman Waxman, in the passage of the Project BioShield Act of 2004 was a credit to each of you. I applaud President Bush for his vision in announcing Project BioShield in his 2003 State of the Union Address. I come before you today to testify on issues of concern to industry regarding the implementation of BioShield. I will reflect on these challenges using anthrax and botulinum vaccines as examples, but I believe they are lessons that can be applied to multiple threats.

BioPort Corporation manufactures BioThrax, the only FDA licensed vaccine for the prevention of anthrax. Our company's history is a successful story of the privatization of the State of Michigan's vaccine production laboratory, which had a 70-year history rich in the development, manufacture and licensure of biologic products. Since privatizing this company in 1998, we have upheld our long-term commitment to the federal government to be a reliable partner for anthrax vaccine as a critically needed biodefense countermeasure. Since 1998, BioThrax has been used to protect more than 1.3 million U.S. military members serving our country around the world. To be clear, this means that over five million doses of BioThrax have been administered in the past seven years. BioThrax and BioPort are proven. Both the product and the company have performed well over time. A safety profile established in more than a million recipients

should not be ignored. Yet the largest contract let under Project BioShield has been awarded for the procurement of an experimental anthrax vaccine administered to fewer than 1,000 recipients. At the same time, the federal government has signed a contract for only five million doses of the FDA licensed anthrax vaccine, and despite all attempts, appears to have only a luke-warm interest in adding meaningful quantities of this vaccine to the Strategic National Stockpile.

It is with this reality that BioPort Corporation must weigh the costs of continuing to manufacture this FDA approved product. As we all know, the principal customer for biodefense countermeasures are government agencies such as the departments of Homeland Security, Health and Human Services and Defense. For a company such as ours, it is critical that the government provides a firm commitment for these products to justify the continued resources necessary to maintain consistent and compliant production facilities and operations. Over the past four years, BioPort has demonstrated its commitment to produce BioThrax at large scale and at favorable pricing. In that effort, we have submitted no fewer than four proposals to decision makers at the Department of Health and Human Services regarding our ability to meet our nation's requirements for anthrax vaccine. As early as December of 2001, BioPort presented HHS with a proposal that could have provided a hundred million doses of licensed anthrax vaccine for the SNS by this time. The notion of “build it and they will come” does not apply to vaccine manufacturing in the biodefense field. The costs are too high, and the risks are too great for the companies and products, particularly when sales are highly dependent upon the U.S. Government procurement decisions.

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As you are aware, Project BioShield has several implicit goals. The first goal is

to increase the number of biodefense companies in the United States. And yet, with respect to anthrax vaccine, there remains only one FDA licensed supplier, BioPort, and only one experimental, non-FDA licensed vaccine. According to public statements made by HHS representatives, the experimental vaccine, under the best case scenario, will not be delivered to the stockpile until fiscal 2007, and even then, will likely not be licensed before 2009, if ever. And most importantly, while described as a "next generation" vaccine, the experimental anthrax vaccine will not have any clear advantages over the existing, FDA licensed vaccine in terms of safety, efficacy, administration or production.

The second implicit goal of BioShield is to create a strong, diversified manufacturing base to avoid another crisis similar to that which occurred in October 2004 with the flu vaccine supply. Again, the procurement process for the anthrax vaccine was designed to limit rather than expand the manufacturing base. The government excluded, from the outset and by design, the only licensed anthrax vaccine manufacturer. Moreover, in the procurement process, the government down selected several other competing manufacturers, resulting in a procurement of a single experimental anthrax vaccine produced at a single plant. By this process, the government has created an environment designed to eliminate a proven product and a proven manufacturer. Thus, the government has truly ignored the bird-in-the-hand while turning to the one-in-the-bush, thereby potentially REDUCING the number of suppliers and amount of countermeasure production capacity. This is precisely the opposite outcome from what was intended under BioShield.

Unfortunately, this experience is being replayed in another government agency's sole source solicitation of an experimental vaccine for the prevention of botulinum,

another Category A threat. The U.S. Government, in announcing its intention to purchase an early stage experimental botulinum vaccine from a single-source, eliminated several competing manufacturers and technologies and reduced the potential for ultimately acquiring a safe and effective vaccine targeted at this threat. Again, BioPort as well as others, has been excluded from this procurement. In our view, this is extraordinary given that BioPort is the only manufacturer that has produced an IND botulinum vaccine for government use over the past 20 years and has notified the government that it stands ready to develop several potential botulinum vaccines with timelines well within those required. Yet the government set specifications in its solicitation expressly designed to eliminate all potential manufacturers -- save one. We fail to understand the government's implementation philosophy given the underlying objective of Project BioShield and the importance of marshalling our nation's resources to develop these critical countermeasures.

Third, Project BioShield is designed to increase the uses for licensed products. Yet, with respect to anthrax vaccine, the purchase of the experimental product does not expand protection to either children or the elderly. Moreover, while the government has stated that a true, "next generation" anthrax vaccine that meets the government's requirements would have a simpler mechanism of delivery (e.g., a skin patch), have a longer shelf-life, not require cold storage, and would provide immunity against a number of lethal toxins caused by the anthrax bacteria, the experimental vaccine has none of these characteristics. This begs the question why the government has committed to an investment of more than $1 billion in a vaccine that does not achieve its own criteria.

Finally, the government, through BioShield, intends to encourage deployment of

the "best in class" countermeasures at competitive prices. And yet again, it took the government until May 5, 2005 - over three and a half years from the anthrax attacks in 2001 - to create a stockpile of FDA licensed anthrax vaccine of 5 million doses, despite the clear requirement to stockpile enough vaccine for 25 million Americans. BioPort has prepared and submitted four proposals to HHS over the last four years to supply FDA licensed vaccine to the stockpile at a cost LOWER than the experimental vaccine (and without the $1 billion federal investment). Yet, HHS intends to procure experimental vaccine for nearly all of the future stockpile from a single supplier at a cost higher than that proposed for the existing FDA licensed anthrax vaccine. Further, the Phase I studies provides no evidence that the experimental vaccine provides any improvement in terms of safety or efficacy over BioThrax. In fact, the published data illustrate that it took both an additional dose and an additional month for the experimental product to provide comparable protection to that of BioThrax. The data also demonstrated a higher rate of systemic reactions than those found with BioThrax. Despite these results, HHS distributed a news release in March 2004 touting the experimental product as safer and more effective. Upon inquiry from Senator Grassley, HHS withdrew the news release from its website in tacit recognition that the news release was inaccurate.

Thus, in each of the implicit goals of Project BioShield, at least with respect to anthrax and botulinum vaccines, Project BioShield has come up short. Considering that fully one-third of the $3.4 billion dollars in currently available funding from Project BioShield has been dedicated to anthrax vaccine, this result is clearly troubling. Despite the availability of an FDA licensed competing vaccine technology, HHS has staked the nation’s protection against the number one biologic threat on an experimental product

that may never be licensed by the FDA. This has made the government and the nation's security against anthrax attacks highly dependent on an unproven technology. Moreover, the government awarded the primary anthrax vaccine stockpile contract to a single vendor, thereby making the nation's security against such attacks dependent on only one manufacturer.

Having highlighted a number of issues, I would like to make a recommendation intended to improve the procurement process involving Project Bioshield funds. The evaluation and eventual procurement of products such as anthrax vaccine is extremely complex and requires the expertise of a multi-disciplined review. Biopharmaceutical companies are managed and operated by multiple disciplines. We count on experienced professionals from the fields of science, medicine, operations, regulatory and compliance to participate in key decisions related to product development. The procurement process for vaccines and other medical countermeasures should follow suit. There is a fundamental need for early oversight in the BioShield procurement process. The risks of failure are too great and the cost of failure is too large to simply continue to operate in a vacuum. Ours is an exacting and demanding business with enormous risk associated. When you add to that the importance of the product candidates involved and the potential to protect and save lives, I cannot imagine a government procurement challenge that is greater than what is at stake with Project BioShield. It therefore requires a sound, disciplined approach that includes expert representation from the medical, scientific, regulatory, and threat assessment perspectives, and is conducted in a manner open to the public. Each procurement should be focused on assuring multiple technologies, multiple companies and multi-year commitments to industry partners. Implementation of a

transparent, multi-disciplinary approach to procurements would also go a long way in allowing the government to build credibility with industry.

In closing, it is essential to recognize that our industry is young and dependent, to a great extent, on a unique customer—the U.S. Government. In the absence of a strong and consistent commitment from that customer, the industry will be characterized by companies that lack a proven track record and that have an inability to sustain over a long period of time. I would restate that BioPort Corporation finds itself at a critical juncture in terms of its ability and willingness to commit resources to a product that lacks a committed customer. I respectfully submit my comments and am willing to answer any questions that members may have.